

In the Claims

Cancel Claim 46. Amend Claims 1, 5, 18, 26, 27, 30, 31, 37, 39, 40, 41, 44, 45, 53, 55, 56 and 70 as follows:

- B1
SUB
C1
1. (Twice amended) A retroviral vector comprising a heterologous gene placed under transcriptional control of an MMTV regulatory sequence, wherein the MMTV regulatory sequence directs expression of the heterologous gene in a cell when the vector is introduced into the cell.
- B2
5. (Twice amended) The retroviral vector according to claim 1 wherein the regulatory sequence contain the 0.6 Kb PstI murine MMTV promoter fragment.
- B9
18. (Twice amended) A capsule encapsulating the packaging cell line according to claim [20] 16, said capsule comprising a porous capsule wall surrounding said packaging cell line, said porous capsule wall being permeable to the [the] viral particles produced by said cells.
- SUB
C1
B10
26. (Twice amended) A method for the expression of a heterologous gene in a human cell comprising introducing a retroviral vector comprising said gene under transcriptional control of an MMTV regulatory sequence into the human cell and maintaining the cell under conditions in which the gene is expressed in the human cell.
27. (Twice amended) The method according to claim 26 wherein the heterologous gene is a therapeutic gene.
- B11
30. (Twice amended) The method according to claim 26 wherein the regulatory sequence contains the 0.6 Kb PstI murine MMTV promoter fragment.
31. (Twice amended) The method according to claim [36] 27 wherein the therapeutic gene is selected from anti-tumor genes and cytokine genes.

Sub D⁵
B12 37. (Twice amended) A method for the treatment of human mammary carcinoma comprising administering to a human in need thereof a DNA construct comprising a therapeutic gene placed under transcriptional control of an MMTV regulatory sequence, wherein the therapeutic gene is expressed in human mammary carcinoma cells and the human mammary carcinoma is treated.

B13 39. (Twice amended) A method for the treatment of human mammary carcinoma comprising administering to a human in need thereof a cell line containing a DNA construct comprising a therapeutic gene placed under transcriptional control of an MMTV regulatory sequence, wherein the therapeutic gene is expressed in human mammary carcinoma cells and the human mammary carcinoma is treated.

40. (Amended) A method for the treatment of human mammary carcinoma comprising implanting into a human in need thereof either in or nearby the site of the tumor a capsule encapsulating a cell line containing a construct comprising a therapeutic gene placed under transcriptional control of an MMTV regulatory sequence, said capsule comprising a porous capsule wall surrounding said cell line, said porous capsule wall being permeable to [the] a heterologous polypeptide encoded by the gene or the viral particles produced by said cells, wherein the heterologous polypeptide is expressed in human mammary carcinoma cells and the human mammary carcinoma is treated.

B14 41. (Amended) A method for expression of a heterologous gene in a human mammary cell [wherein expression of said] comprising introducing a vector comprising the gene [is placed] under transcriptional control of a WAP regulatory sequence into the cell and maintaining the cell under conditions in which the heterologous gene is expressed in the human mammary cell.

B15 44. (Amended) The method according to claim 41 wherein the regulatory sequence comprises the proximal 445 bp of the murine WAP promoter including the transcription initiation site.

- B15
Control
45. (Amended) The method according to claim 41 wherein the regulatory sequence contains the 320 bp XhoI/XbaI fragment of the murine WAP promoter region.
-

- B16
53. (Amended) A retroviral vector comprising a heterologous gene placed under transcriptional control of a WAP regulatory sequence, wherein the WAP regulatory sequence directs expression of the heterologous gene in a cell when the vector is introduced into the cell.
-

- B17
55. (Amended) The retroviral vector according to claim 53 wherein the regulatory sequence comprises the proximal 445 bp pf the murine WAP promoter including the transcription initiation site.

56. (Amended) The retroviral vector according to claim 53 wherein the regulatory sequence contains the 320 bp XhoI/XbaI fragment of the murine WAP promoter region.
-

- sub 6
B18
70. (Amended) A method for the treatment of human mammary carcinoma comprising administering to a human in need thereof a DNA construct comprising a therapeutic gene placed under transcriptional control of [an] a WAP regulatory sequence, wherein the therapeutic gene is expressed in human mammary carcinoma cells and the human mammary carcinoma is treated.
-

sub
C6
B19

[Please add the following claims:]

- 74. A retroviral vector comprising a heterologous gene placed under transcriptional control of a rodent MMTV regulatory sequence, wherein the MMTV regulatory sequence directs expression of the heterologous gene in a human mammary cell when the vector is introduced into the cell.

75. The retroviral vector according to claim 74 wherein the heterologous gene is a therapeutic gene.

76. The retroviral vector according to claim 74 wherein the retroviral vector comprises a 5'LTR region of the structure U3-R-U5; at least one coding sequence coding for the heterologous gene; and a 3' LTR region comprising a completely or partially deleted U3 region wherein said deleted region has been replaced by a polylinker containing the MMTV regulatory sequence followed by the R and U5 region, said heterologous gene being under transcriptional control of the MMTV regulatory sequence.
77. The retroviral vector according to claim 75 wherein the therapeutic gene is selected from the group consisting of: anti-tumor genes and cytokine genes.
78. A recombinant retroviral particle produced by culturing a packaging cell line harbouring the retroviral vector according to claim 74 and one or more constructs coding for proteins required for a genome of said retroviral vector to be packaged.
79. A retroviral provirus carrying a construct comprising a heterologous gene placed under transcriptional control of a rodent MMTV regulatory sequence.
80. A packaging cell line harbouring a retroviral vector construct according to claim 74 and one or more constructs coding for proteins required for the genome of said retroviral vector to be packaged.
81. An isolated human cell comprising a retroviral provirus according to claim 79.
82. A retroviral vector comprising a heterologous gene placed under transcriptional control of a rodent WAP regulatory sequence wherein the WAP regulatory sequence directs expression of the heterologous gene in a human mammary carcinoma cell when the vector is introduced into the cell.
83. The retroviral vector according to claim 82 wherein said heterologous gene is a therapeutic gene.

B19
Contd

SUB
877

See 210

84. The retroviral vector according to claim 82 wherein the retroviral vector comprises a 5'LTR region of the structure U3-R-U5; at least one coding sequence coding for the heterologous gene; and a 3' LTR region comprising a completely or partially deleted U3 region wherein said deleted region has been replaced by a polylinker containing the WAP regulatory sequence followed by the R and U5 region, said heterologous gene being under transcriptional control of the WAP regulatory sequence.
85. The retroviral vector according to claim 83 wherein the therapeutic gene is selected from the group consisting of: anti-tumor genes and cytokine genes.
86. A recombinant retroviral particle produced by culturing a packaging cell line harboring a retroviral vector construct according to claim 82 and one or more constructs coding for the proteins required for the genome of said retroviral vector to be packaged.
87. A retroviral provirus carrying a construct comprising a heterologous gene placed under transcriptional control of a rodent WAP regulatory sequence.
88. A packaging cell line harboring a retroviral construct according to claim 82 and one or more constructs coding for the proteins required for the genome of said retroviral vector to be packaged.
89. An isolated human cell comprising a retroviral provirus according to claim 87.
90. A capsule encapsulating the packaging cell line according to claim 88, said capsule comprising a porous wall surrounding said packaging cell line, said porous capsule wall being permeable to the heterologous polypeptide or the viral particles produced by said cells.
91. A method for the expression of a heterologous gene in a human cell comprising introducing a retroviral vector comprising said gene under transcriptional control of a rodent MMTV regulatory sequence into the human cell and maintaining the cell under conditions in which the gene is expressed in the human cell.